

8

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Page 1

21 C.F.R. § 101.13

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Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter I. Food and Drug Administration,
Department of Health and Human Services
(Refs & Annos)

Subchapter B. Food for Human Consumption

Part 101. Food Labeling (Refs & Annos)

Subpart A. General Provisions

**→§ 101.13 Nutrient content
claims--general principles.**

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in

association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in parts 101, 105, or 107 of this chapter.

(4) Reasonable variations in the spelling of the terms defined in part 101 and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(5) For dietary supplements, claims for calories, fat, saturated fat, and cholesterol may not be made on products that meet the criteria in § 101.60(b)(1) or (b)(2) for "calorie free" or "low calorie" claims, except, in the case of calorie claims, when an equivalent amount of a similar dietary supplement (e.g., another protein supplement) that the labeled food resembles and for which it substitutes, normally exceeds the definition for "low calorie" in § 101.60(b)(2).

(c) Information that is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" food is one that may be used interchangeably with another food that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

21 C.F.R. § 101.13

(1) If there is a difference in performance characteristics that materially limits the use of the food, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with § 101.2(c)(5), in which case the disclaimer may be in type of not less than one thirty-second of an inch.

(e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food, may bear such a claim (e.g., "low sodium potato chips").

(2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium-free food").

(f) A nutrient content claim shall be in type size no larger than two times the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) [Reserved]

(h)(1) If a food, except a meal product as defined in

§ 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form), then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: "See nutrition information for ___ content" with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., "See nutrition information for fat content."

(2) If a food is a meal product as defined in § 101.13(l), and contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in § 101.13(m), and contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(4)(i) The disclosure statement "See nutrition information for ___ content" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by § 101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclosure statement shall be no less than

21 C.F.R. § 101.13

one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with § 101.2(c)(2), in which case the disclosure statement may be in type of not less than one thirty-second of an inch.

(ii) The disclosure statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§ 101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the disclosure statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

(iii) If a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single disclosure statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(i) Except as provided in § 101.9 or § 101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is consistent with a definition for a claim, as provided in subpart D of this part, for the nutrient that the label addresses. Such a claim might be, "less than 3 g of fat per serving;"

(2) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not "low" in or a "good source" of the nutrient, such as "only 200 mg sodium per serving, not a low sodium food." The disclaimer must be in

easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch unless the package complies with § 101.2(c)(5), in which case the disclaimer may be in type of not less than one thirty-second of an inch, or

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with § 101.62(b)(6).

(j) A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food. These statements shall be known as "relative claims" and include "light," "reduced," "less" (or "fewer"), and "more" claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared to an amount of nutrient in an appropriate reference food as specified below.

(i)(A) For "less" (or "fewer") and "more" claims, the reference food may be a dissimilar food within a product category that can generally be substituted for one another in the diet (e.g., potato chips as reference for pretzels, orange juice as a reference for vitamin C tablets) or a similar food (e.g., potato chips as reference for potato chips, one brand of multivitamin as reference for another brand of multivitamin).

(B) For "light," "reduced," "added," "extra," "plus," "fortified," and "enriched" claims, the reference food shall be a similar food (e.g., potato chips as a reference for potato chips, one brand of multivitamin for another brand of

21 C.F.R. § 101.13

multivitamin), and

(ii)(A) For "light" claims, the reference food shall be representative of the type of food that includes the product that bears the claim. The nutrient value for the reference food shall be representative of a broad base of foods of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the food type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than "light," including "less" and "more" claims, the reference food may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section, or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting label is internally consistent to (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information and the declaration of the percentage of nutrient by which the food has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For foods bearing relative claims:

(i) The label or labeling must state the identity

of the reference food and the percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient in the labeled food differs (e.g., "50 percent less fat than (reference food)" or "1/3 fewer calories than (reference food)"),

(ii) This information shall be immediately adjacent to the most prominent claim. The type size shall be in accordance with paragraph (h)(4)(i) of this section.

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that in the reference food; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the requirement for a "low" claim for that nutrient (e.g., 3 g fat or less).

(k) The term "modified" may be used in the

21 C.F.R. § 101.13

statement of identity of a food that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "Modified fat cheesecake"). This statement of identity must be immediately followed by the comparative statement such as "Contains 35 percent less fat than _____." The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a "meal product shall be defined as a food that:

(1) Makes a major contribution to the total diet by:

(i) Weighing at least 10 ounces (oz) per labeled serving; and

(ii) Containing not less than three 40-g portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts group; except that;

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, or meal. Such representations may be made either by statements, photographs, or vignettes.

(m) For purposes of making a claim, a "main dish product" shall be defined as a food that:

(1) Makes a major contribution to a meal by

(i) Weighing at least 6 oz per labeled serving; and

(ii) Containing not less than 40 g of food, or combinations of foods, from each of at least two of the following four food groups, except as noted in paragraph (m)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts groups; except that:

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces) gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a main dish (e.g., not a beverage or a dessert). Such representations may be made either by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with § 101.9, § 101.10, or § 101.36, as applicable, shall be provided for any food for which a nutrient content claim is made.

(o) Except as provided in § 101.10, compliance with requirements for nutrient content claims in this section and in the regulations in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9.

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in

21 C.F.R. § 101.13

the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 101.12(g) (e.g., "very low sodium, 35 mg or less per 240 milliliters (8 fl oz.)").

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size in accordance with paragraph (h)(4)(i) of this section.

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989, may continue to be used as part of that brand name for such product, provided that they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act). However, foods bearing such claims must comply with section 403(f), (g), and (h) of the act;

(2) A soft drink that used the term diet as part of its brand name before October 25, 1989, and whose use of that term was in compliance with § 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act. Such claims are exempt from the requirements of section 403(r)(2) of the act (e.g., the disclosure statement also required by § 101.13(h)). Soft drinks marketed after October 25, 1989, may use the term "diet" provided they are in compliance with the current § 105.66 of this chapter and the requirements of § 101.13.

(3)(i) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 101.9 may be made on the label or in labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral unless such claim is expressly prohibited by regulation

under section 403(r)(2)(A)(vi) of the act.

(ii) Percentage claims for dietary supplements. Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which a reference daily intake (RDI) or daily reference value (DRV) has not been established may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. All such claims shall be accompanied by any disclosure statement required under paragraph (h) of this section.

(A) Simple percentage claims. Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV, the statement of the actual amount of the dietary ingredient per serving shall be declared next to the percentage statement (e.g., "40 percent omega-3 fatty acids, 10 mg per capsule").

(B) Comparative percentage claims. Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV and the statement draws a comparison to the amount of the dietary ingredient in a reference food, the reference food shall be clearly identified, the amount of that food shall be identified, and the information on the actual amount of the dietary ingredient in both foods shall be declared in accordance with paragraph (j)(2)(iv) of this section (e.g., "twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)").

(4) The requirements of this section do not apply to:

(i) Infant formulas subject to section 412(h) of the act; and

(ii) Medical foods defined by section 5(b) of the Orphan Drug Act.

(5) A nutrient content claim used on food that

21 C.F.R. § 101.13

is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

(i) Such claim is exempt from the requirements for disclosure statements in paragraph (h) of this section and §§ 101.54(d), 101.62(c), (d)(1)(ii)(D), (d)(2)(iii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C); and

(ii) In lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. This reasonable basis may derive from recognized data bases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (e.g., types and amounts of ingredients, cooking temperatures, etc.). Firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim; and

(iii) A term or symbol that may in some contexts constitute a claim under this section may be used, provided that the use of the term or symbol does not characterize the level of a nutrient, and a statement that clearly explains the basis for the use of the term or symbol is prominently displayed and does not characterize the level of a nutrient. For example, a term such as "lite fare" followed by an asterisk referring to a note that makes clear that in this restaurant "lite fare" means smaller portion sizes than normal; or an item bearing a symbol referring to a note that makes clear that this item meets the criteria for the dietary guidance established by a recognized dietary authority would not be considered a nutrient

content claim under § 101.13.

(6) Nutrient content claims that were part of the common or usual names of foods that were subject to a standard of identity on November 8, 1990, are not subject to the requirements of paragraphs (b) and (h) of this section or to definitions in subpart D of this part.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the Food and Drug Administration. Petitions requesting approval of such a claim may be submitted under § 101.69(o).

(8) The term fluoridated, fluoride added or with added fluoride may be used on the label or in labeling of bottled water that contains added fluoride.

[49 FR 15534, April 18, 1984; 58 FR 2410, Jan. 6, 1993; 58 FR 17341, 17342, April 2, 1993; 58 FR 44030, Aug. 18, 1993; 59 FR 393, Jan. 4, 1994; 59 FR 15051, March 31, 1994; 60 FR 17205, April 5, 1995; 61 FR 11731, March 22, 1996; 61 FR 40332, Aug. 2, 1996; 61 FR 67452, Dec. 23, 1996; 62 FR 31339, June 9, 1997; 62 FR 49867, Sept. 23, 1997; 63 FR 14818, March 27, 1998; 63 FR 26980, May 15, 1998]

21 C. F. R. § 101.13, **21 CFR § 101.13**

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9

Westlaw.

Page 1

21 C.F.R. § 101.14

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Subchapter B. Food for Human Consumption

Part 101. Food Labeling (Refs & Annos)

Subpart A. General Provisions

→§ 101.14 Health claims: general requirements.

(a) Definitions. For purposes of this section, the following definitions apply:

(1) Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

(2) Substance means a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement that includes vitamins, minerals, herbs, or other similar nutritional substances.

(3) Nutritive value means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) Disqualifying nutrient levels means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(i) The levels for a meal product as defined in § 101.13(l) are 26.0 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per label serving size, and

(ii) The levels for a main dish product as defined in § 101.13(m) are 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per label serving size.

(5) Disease or health-related condition means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to § 101.14 or § 101.70).

(b) Eligibility. For a substance to be eligible for a health claim:

(1) The substance must be associated with a

21 C.F.R. § 101.14

disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

(2) If the substance is to be consumed as a component of a conventional food at decreased dietary levels, the substance must be a nutrient listed in 21 U.S.C. 343(q)(1)(C) or (q)(1)(D), or one that the Food and Drug Administration (FDA) has required to be included in the label or labeling under 21 U.S.C. 343(q)(2)(A); or

(3) If the substance is to be consumed at other than decreased dietary levels:

(i) The substance must, regardless of whether the food is a conventional food or a dietary supplement, contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

(ii) The substance must be a food or a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act.

(c) Validity requirement. FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(d) General health claim labeling requirements.

(1) When FDA determines that a health claim meets the validity requirements of paragraph (c) of this section, FDA will propose a regulation in subpart E of this part to authorize the use of that claim. If the claim pertains to a substance not provided for in § 101.9 or § 101.36, FDA will propose amending that regulation to include declaration of the substance.

(2) When FDA has adopted a regulation in subpart E of this part providing for a health claim, firms may make claims based on the regulation in subpart E of this part, provided that:

(i) All label or labeling statements about the substance-disease relationship that is the subject of the claim are based on, and consistent with, the conclusions set forth in the regulations in subpart E of this part;

(ii) The claim is limited to describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition;

(iii) The claim is complete, truthful, and not misleading. Where factors other than dietary intake of the substance affect the relationship between the substance and the disease or health-related condition, such factors may be required to be addressed in the claim by a specific regulation in subpart E of this part;

(iv) All information required to be included in the claim appears in one place without other intervening material, except that the principal display panel of the label or labeling may bear the reference statement, "See _____ for information about the relationship between _____ and _____," with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing elsewhere on the other

21 C.F.R. § 101.14

labeling, Provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appears on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material;

(v) The claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet; and

(vi) If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. To meet this requirement, if a definition for use of the term low has been established for that substance under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "low" has been established, the level of the substance must meet the level established in the regulation authorizing the claim; or

(vii) If the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance is sufficiently high and in an appropriate form to justify the claim. To meet this requirement, if a definition for use of the term high for that substance has been established under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "high" has been established (e.g., where the claim pertains to a food either as a whole food or as an ingredient in another food), the claim must specify the daily dietary intake necessary to achieve the claimed effect, as established in the regulation authorizing the claim; *Provided that*:

(A) Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily

consumed, and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors. A serving of ___ ounces of this product conforms to such a diet.").

(B) Where the food that bears the claim is sold in a restaurant or in other establishments in which food that is ready for immediate human consumption is sold, the food can meet the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section if the firm that sells the food has a reasonable basis on which to believe that the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section and provides that basis upon request.

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements, in accordance with § 101.36.

(e) Prohibited health claims. No expressed or implied health claim may be made on the label or in labeling for a food, regardless of whether the food is in conventional food form or dietary supplement form, unless:

(1) The claim is specifically provided for in subpart E of this part; and

(2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part;

(3) None of the disqualifying levels identified in paragraph (a)(4) of this section is exceeded in the food, unless specific alternative levels have been established for the substance in subpart E of this part; or unless FDA has permitted a claim despite the fact that a

21 C.F.R. § 101.14

disqualifying level of a nutrient is present in the food based on a finding that such a claim will assist consumers in maintaining healthy dietary practices, and, in accordance with the regulation in subpart E of this part that makes such a finding, the label bears a disclosure statement that complies with § 101.13(h), highlighting the nutrient that exceeds the disqualifying level;

(4) Except as provided in paragraph (e)(3) of this section, no substance is present at an inappropriate level as determined in the specific provision authorizing the claim in subpart E of this part;

(5) The label does not represent or purport that the food is for infants and toddlers less than 2 years of age except if the claim is specifically provided for in subpart E of this part; and

(6) Except for dietary supplements or where provided for in other regulations in part 101, subpart E, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

(f) The requirements of this section do not apply to:

(1) Infant formulas subject to section 412(h) of the Federal Food, Drug, and Cosmetic Act, and

(2) Medical foods defined by section 5(b) of the Orphan Drug Act.

(g) Applicability. The requirements of this section apply to foods intended for human consumption that are offered for sale, regardless of whether the foods are in conventional food form or dietary supplement form.

[58 FR 2533, Jan. 6, 1993; 58 FR 17097, April 1, 1993; 58 FR 44038, Aug. 18, 1993; 59 FR 425, Jan. 4, 1994; 59 FR 15050, March 31, 1994; 61 FR 40332, Aug. 2, 1996; 62 FR 49867, Sept. 23, 1997; 63 FR 26980, May 15, 1998; 66 FR 17358, March 30, 2001]

21 C. F. R. § 101.14, **21 CFR § 101.14**

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10

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Page 1

21 C.F.R. § 101.22

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Effective: [See Text Amendments]

Code of Federal Regulations Currentness

Title 21. Food and Drugs

Chapter I. Food and Drug Administration,
Department of Health and Human Services
(Refs & Annos)

Subchapter B. Food for Human Consumption

Part 101. Food Labeling (Refs & Annos)

Subpart B. Specific Food Labeling
Requirements**→§ 101.22 Foods; labeling of spices,
flavorings, colorings and chemical
preservatives.**

(a)(1) The term artificial flavor or artificial flavoring means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in §§ 172.515(b) and 182.60 of this chapter except where these are derived from natural sources.

(2) The term spice means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in § 182.10 and Part 184 of this chapter, such as the following:

Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white;

Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric.

Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as "spice and coloring" unless declared by their common or usual name.

(3) The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and Part 184 of this chapter, and the substances listed in § 172.510 of this chapter.

(4) The term artificial color or artificial coloring means any "color additive" as defined in § 70.3(f) of this chapter.

(5) The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food or on its container or wrapper, or on any two or all three of these, as may be necessary to

21 C.F.R. § 101.22

render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food. The specific artificial color used in a food shall be identified on the labeling when so required by regulation in Part 74 of this chapter to assure safe conditions of use for the color additive.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k).

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state "All flavor ingredients contained in this product are approved for use in a regulation of

the Food and Drug Administration." Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., "strawberry flavor", "banana flavor", or "natural strawberry flavor". In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., "natural and artificial strawberry flavor". In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., "artificial strawberry flavor".

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as "spice", "natural flavor", or "artificial flavor", or any combination thereof, as the case may be.

(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of § 101.100(a)(3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name "salt."

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name "monosodium glutamate."

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food

21 C.F.R. § 101.22

may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(7) Because protein hydrolysates function in foods as both flavorings and flavor enhancers, no protein hydrolysate used in food for its effects on flavor may be declared simply as "flavor," "natural flavor," or "flavoring." The ingredient shall be declared by its specific common or usual name as provided in § 102.22 of this chapter.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be

immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial vanilla", "artificially flavored strawberry", or "grape artificially flavored".

(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

21 C.F.R. § 101.22

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food, e.g., "artificially flavored vanilla and strawberry".

(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor, e.g., "artificially flavored fruit punch".

(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it. The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor user shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of three years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized office or employee of the Food and Drug

Administration or any other employee acting on behalf of the Secretary of Health and Human Services. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable: *Provided*, That, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and

21 C.F.R. § 101.22

ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: *Provided*, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to § 101.100 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention".

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to §§ 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

(1) A color additive or the lake of a color additive subject to certification under 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the "FD&C" prefix or the term "No." in the declaration, but the term "Lake" shall be included in the declaration of the lake of the certified color

additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food).

Alternatively, such color additives may be declared as "Colored with _____" or "_____ color", the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

(3) When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for the color additive. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

[42 FR 14308, March 15, 1977, as amended at 43 FR 3963, Jan. 19, 1979; 44 FR 37220, June 26, 1979; 54 FR 24891, June 12, 1989; 58 FR 2875, Jan. 6, 1993; 63 FR 14818, March 27, 1998]

21 C. F. R. § 101.22, **21 CFR § 101.22**

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